UNITED STATES DISTRICT COURT
DISTRICT OF NORTHERN TEXAS
DALLAS DIVISION

BERNARD MULDOON, **Plaintiff,** **v.** **DEPUY ORTHOPAEDICS, INC, JOHNSON & JOHNSON,** **Defendants.**	§ § § § § § § § § § § § § § § § § § § §	**CIVIL ACTION No.** **COMPLAINT** **JURY TRIAL DEMANDED**

SUMMARY OF PLAINTIFF'S ALLEGATIONS

1. This is a civil action being brought by Plaintiff, Bernard Muldoon, a private person, on his own behalf, against Defendants, DePuy Orthopaedics, Inc. and Johnson & Johnson.

2. Bernard Muldoon has suffered damages as a result of Defendants' wrongful conduct in connection with the development, design, testing, manufacture, distribution, and sale of the metal-on-metal DePuy Pinnacle™ Hip Replacement System ("DePuy Pinnacle").

3. As a result of the dangerous and/or defective condition of the DePuy Pinnacle that was sold by Defendants and implanted in Plaintiff, Plaintiff has suffered, and continues to suffer, serious bodily injury and has incurred, and continues to incur,

medical expenses to treat his injuries and condition.

PARTIES

4. Plaintiff, Bernard Muldoon, is a citizen and resident of the State of Connecticut.

5. Defendant, DePuy Orthopaedics, Inc. ("DePuy"), is a corporation organized and incorporated in Indiana with its primary place of business in Warsaw, Indiana. DePuy developed, designed, tested, manufactured, distributed and sold the DePuy Pinnacles that are the subject of this lawsuit.

6. Defendant, Johnson & Johnson ("J&J"), is a corporation organized and existing under the laws of New Jersey with its primary place of business in New Jersey. J&J developed, designed, tested, manufactured, distributed and sold the DePuy Pinnacles that are the subject of this lawsuit.

7. Defendants, DePuy and J&J, conduct business in the State of Connecticut.

8. DePuy is a wholly owned subsidiary of the Defendant, J&J.

9. DePuy and J&J are collectively referred to herein as "Defendants."

JURISDICTION AND VENUE

10. This court has subject matter jurisdiction over this action under 28 U.S.C. § 1332. The matter in controversy is between citizens of different states and the amount in controversy exceeds $75,000 exclusive of interests and costs. This court also has supplemental jurisdiction over state law claims under 28 U.S.C. § 1367.

11. The venue for this action lies in the District of Connecticut. Venue is proper in this district under 28 U.S.C. § 1391(a). The events giving rise to the claims set forth in this complaint occurred in this district.

FACTUAL BACKGROUND

A. DEPUY'S DEPUY PINNACLE HAS NOT BEEN ADEQUATELY TESTED

12. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

13. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

14. The DePuy Pinnacle has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular cup when most other hip replacements use a polyethylene plastic acetabular cup. By using a metal acetabular cup and a metal femoral ball, the DePuy Pinnacle forces metal to rub against metal with the full weight and pressure of the human body. Because of Defendants' defective design of the DePuy Pinnacle, hundreds of patients have been forced to undergo surgeries to replace the failed hip implants.

15. The Defendants failed to adequately test the DePuy Pinnacle. Adequate testing of the DePuy Pinnacle would have revealed the dangerous and defective design of the

implant.

B. DEPUY'S DEPUY PINNACLE WAS NOT APPROVED BY THE FDA

16. The design of the DePuy Pinnacle was not sufficiently tested by the Defendants, and it was never approved by the FDA as being safe or effective for the products' intended purpose.

17. The DePuy Pinnacle is a Class III medical device. Class III devices are those that operate to sustain human life, are of substantial importance in preventing impairment of human health, or pose potentially unreasonable risks to patients.

18. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA"), in theory, require Class III medical devices, including the DePuy Pinnacle, to undergo premarket approval by the FDA, a process which obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA.

19. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

20. The FDA may grant premarket approval only if it finds that there is reasonable

assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

21. A medical device on the market prior to the effective date of the MDA – a so called "grandfathered" device – was not required to undergo premarket approval.

22. In addition, a medical device marketed *after* the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a "grandfathered" pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA of its intent to market a device at least 90 days prior to the device's introduction on the market, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

23. Most new Class III devices enter the market through the 510(k) process.

24. The MDA does not require an FDA determination that the device is in fact, substantially equivalent to a grandfathered device.

25. Instead of assuring the safety of the DePuy Pinnacle through clinical trials, DePuy sought to market its DePuy Pinnacle without conducting any clinical trials by obtaining FDA approval under section 510(k).

26. By telling the FDA that the DePuy Pinnacle's design was "substantially equivalent" to other hip products on the market, DePuy was able to avoid the safety review required for premarket approval under FDA regulations including clinical trials.

27. In October 2000, the FDA approved the metal-on-metal DePuy Pinnacle for sale

by means of the abbreviated 510(k) process and consequently, the FDA did not require the DePuy Pinnacle to undergo clinical trials.

28. Significantly, unlike the premarket approval process, the 510(k) notification process does not call for scrutiny – or even clinical testing – of a device's safety and effectiveness.

29. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness.

30. Thus, the FDA's finding of "substantial equivalence" had nothing to do with reviewing the DePuy Pinnacle's safety and effectiveness, but rather only a determination of equivalence to devices that themselves underwent no safety and effectiveness review.

C. DOCTORS ACKNOWLEDGE DANGERS OF METAL-ON-METAL TOTAL HIP REPLACEMENTS

31. Leading orthopedic surgeons in the United States have virtually stopped using metal-on-metal hip implants because a significant percentage of patients who receive these implants experience early failure, dislocation and disarticulation. Many patients also suffer severe tissue loss, infection and irreversible bone damage caused by the failure of metal-on-metal hip implants, metallosis and biologic toxicity.

32. The Medicines and Healthcare products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA required doctors to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

33. Because of the problems associated with the relative difficulty in positioning the implants and because of demonstrated premature and excessive wear, the Journal of Arthroplasty issued a statement urging doctors to use any metal-on-metal hip replacement only with "great caution, if at all."

34. The Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants. Despite scientific evidence to the contrary, DePuy continues to misrepresent the DePuy Pinnacle™ Hip Replacement System as a high-quality, safe and effective hip replacement product.

35. In May 2011, the FDA demanded that medical device companies, which manufacture and deliver metal-on-metal devices, conduct post-marketing studies regarding the safety of metal-on-metal devices due to concerns about metal poisoning.

D. KNOWN DANGERS OF THE DEPUY METAL-ON-METAL HIP REPLACEMENTS

36. Defendants have known for years that implantation of their DePuy Pinnacle metal-on-metal total hip replacement system results in metallosis, biologic toxicity and an early and high failure rate.

37. Implantation of Defendants' metal-on-metal total hip replacement systems, including the DePuy Pinnacle, results in the release of high levels of toxic metal ions into every hip implant patient's tissue and bloodstream.

38. Particles released by friction of the metal-on-metal surfaces also results in metallosis, tissue death and the growth of tumors. This friction wear is especially

pronounced in the early "wear in" period, particularly on the leading edge of the metal acetabular cup. In the industry this is commonly referred to as "edge wear" or "edge loading."

39. Defendants' metal-on-metal total hip replacement systems are also defective in that because of their design, "proper" placement is exceedingly difficult for even experienced and competent surgeons to successfully accomplish. Without near perfect placement, the problems of edge wear and edge loading are exacerbated making metallosis more severe and early failure even more common.

40. In the DePuy Pinnacle, as well as the DePuy ASR, the edge wear is further exacerbated by the low clearance between the metal head of the implant and the metal of the acetabular liner which increases contact between the two metal components. The DePuy Pinnacle and the DePuy ASR have the lowest clearance rate of all metal-on-metal implants which causes a higher revision rate in these implants compared to other metal-on-metal hip implant models.

41. Once the body is exposed to and absorbs the toxic metallic ions and particulate debris from the DePuy Pinnacle metal-on-metal total hip replacement system, inflammation occurs, causing severe pain, infection, death of the surrounding tissue and bone loss. Tumors also develop.

E. DEFENDANTS RECALL NEWER "SUBSTANTIALLY EQUIVALENT" DEPUY METAL-ON-METAL TOTAL HIP REPLACEMENT

42. In December 2009, the DePuy ASR metal-on-metal total hip replacement system was withdrawn from the Australian market due to its high failure rate. Like the substantially equivalent DePuy Pinnacle metal-on-metal total hip replacement system, the

defective DePuy ASR is prone to early failure and causes metallosis and cobalt toxicity resulting in serious health problems.

43. In March 2010, The New York Times documented these serious defects and the severe physical harms caused by Defendants' "substantially equivalent" DePuy ASR metal-on-metal total hip replacement system. The same defects, risks and resultant harms found with the use of the DePuy ASR are also found with the use of the DePuy Pinnacle metal-on-metal total hip replacement system – early catastrophic failure occurs due to the metal-on-metal corrosive and frictional wear resulting in metallosis, revision surgeries and the other known catastrophic health problems.

44. In August 2010, Defendants acknowledged the high failure rate of the substantially equivalent DePuy ASR metal-on-metal total hip replacement system and recalled more than 90,000 DePuy metal-on-metal systems from the worldwide market.

45. Like the substantially equivalent Pinnacle, the recalled DePuy ASR metal-on-metal total hip replacement system was never FDA approved. Instead, it received 510(k) certification only after Defendants claimed that it was "substantially equivalent" to the earlier defective DePuy Pinnacle metal-on-metal total hip replacement system implanted in the Plaintiff.

46. These systems are indeed substantially equivalent not only in their difficulty to implant in patients but also in their propensity to catastrophically fail early. Predictably, the biologic toxicity caused by these implants results in serious health problems that are also substantially equivalent. The defective DePuy Pinnacle metal-on-metal total hip replacement system should be recalled for the same reasons Defendants recalled the defective DePuy ASR system.

47. It is estimated that perhaps only 5% of Class III medical device failures are ever reported to the FDA. Despite this fact, the FDA has received notice of hundreds of self-reported cases of critical failures and physical harm to patients implanted with the DePuy Pinnacle metal-on-metal total hip replacement systems implanted in Mr. Muldoon . As with the recalled DePuy ASR, the reports of the harm caused by the defective Pinnacle include catastrophic failures, premature wear, dislocation, disarticulation, disassembly, metallosis and serum toxicity.

F. THE DEFECTIVE DEPUY PINNACLE AND THE DEFENDANTS' CONDUCT CAUSED INJURIES AND SUBSTANTIAL DAMAGE TO PLAINTIFF

48. On June 4, 2009, Mr. Muldoon underwent a left total hip replacement operation at UConn Health Center in Farmington, Connecticut performed by Dr. Roy Beebe. During the operation a metal-on-metal DePuy Pinnacle was implanted in his left hip.

49. At all times mentioned herein, the DePuy Pinnacle implanted into the Plaintiff was without substantial and/or unforeseeable change from the condition in which it was manufactured, distributed and/or sold by the Defendants.

50. The DePuy Pinnacle that was implanted into Mr. Muldoon resulted in injuries to his left hip joint, including erosion of the acetabulum, femur and surrounding structures, resulting in severe pain and a limp; metallosis; fluid buildup in his left hip; a pseudo tumor; pain and mental anguish, some or all of which injuries are, or are likely to be, permanent, or to have permanent effects.

51. As a further consequence of these injuries, on December 6, 2012, Mr. Muldoon was forced to undergo an additional total hip replacement surgery in order to revise the DePuy Pinnacle implanted in his left hip, which was defective and/or dangerous, and

may, in the future, require further treatment for these injuries and/or complications thereof.

52. By 2006, Defendants were on notice that the DePuy Pinnacle was defective. However, it was not until November of 2012, that the Plaintiff became aware that the DePuy Pinnacle was defective.

53. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

54. Further revision surgery will subject Mr. Muldoon to much greater risks of future complications than he had before the revision surgery. For example, several studies have found that revision surgery has a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent a original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al.* Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

55. As a direct and proximate result of the failure of his defective DePuy Pinnacle and the Defendants' wrongful conduct, Mr. Muldoon sustained and continues to suffer

economic damages (including medical expenses and hospital expenses and lost income), severe and possibly permanent injuries, disability, disfigurement, pain, suffering and emotional distress. Furthermore, Mr. Muldoon has a risk of future harm and/or a reasonable fear of future harm. As a result, Mr. Muldoon has sustained and will continue to sustain damages in an amount to be proven at trial.

CONNECTICUT PRODUCT LIABILITY ACT

56. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint and further alleges:

57. The Defendants are product sellers, in that they are in the business of manufacturing, wholesaling, distributing and/or retailing, as defined by Connecticut General Statutes § 52-572m, hip replacement implants, including DePuy Pinnacles.

58. The Defendants were responsible for the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging and/or labeling of DePuy Pinnacles, including that which injured the Plaintiff.

59. Pursuant to Connecticut General Statutes § 52-572m et seq, the Defendants are legally responsible to the Plaintiff for the injuries and losses alleged herein, in one or more of the following ways:

a. in that the DePuy Pinnacle was defective and unreasonably dangerous; and/or

b. in that the DePuy Pinnacle was defective and unreasonably dangerous in that it released toxic metal ions into the tissue and/or bloodstream of hip implant recipients, including the Plaintiff; and/or

c. in that the Defendants manufactured, distributed and/or sold the DePuy Pinnacle with an abrading

metal-on-metal design that caused shearing and/or release of metal ions; and/or

d. in that the DePuy Pinnacle was not fit and/or safe for the uses and purposes intended; and/or

e. in that the DePuy Pinnacle was not fit for the particular purposes for which it was distributed and/or sold by the Defendants; and/or

f. in that the DePuy Pinnacle was defective and unreasonably dangerous, pursuant to Section 52-572q of the General Statutes, due to lack of adequate warnings and/or instructions; and/or

g. in that the Defendants manufactured, distributed and/or sold the DePuy Pinnacle without adequately, sufficiently, or thoroughly testing the same; and/or

h. in that the Defendants failed to take proper measures to establish the safety of the DePuy Pinnacle prior to marketing the same for implantation in patients, including the Plaintiff; and/or

i. in that the Defendants failed to properly and adequately consider and/or address the risks and dangers previously exhibited by other medical devices of similar materials, before manufacturing, distributing, selling and/or marketing the DePuy Pinnacle for implantation in patients, including the Plaintiff; and/or

j. in that the DePuy Pinnacle implanted in the Plaintiff were defective and/or unreasonably dangerous in that it was highly and unreasonably susceptible to early failure and/or a need for early replacement; and/or

k. in that the Defendants knew, or should have known, that the DePuy Pinnacle was unsafe and unfit for use by reason of the dangers to its users but they sold the products for implantation in patients, including the Plaintiff, anyway; and/or

l. in that the Defendants failed to properly and adequately warn the Plaintiff and/or his health care providers of the dangers of the DePuy Pinnacle; and/or

m. in that the Defendants failed to recall the DePuy Pinnacle when they first knew, or should have known, that the device was unreasonably dangerous and defective, thereby causing the dangerous and defective device to be implanted in further patients, including the plaintiff; and/or

n. in that they failed to provide proper and adequate instructions to implanting surgeons; and/or

o. in that the Defendants continued to manufacture, distribute, sell, market and/or encourage the use of their DePuy Pinnacles, although they knew, or should have known, of their dangerous propensities; and/or

p. in that the Defendants failed to properly appraise and/or report the risks and dangers of the DePuy Pinnacles, leading to its use in patients, including the Plaintiff, although it was unreasonably dangerous; and/or

q. in that the Defendants breached their express warranties to the Plaintiff representing that the DePuy Pinnacle was safe, effective, fit, and proper for its intended uses in order to induce its purchase or use; and/or

r. in that the Defendants breached their implied warranties of merchantability when they impliedly warranted to Plaintiff that the DePuy Pinnacle was fit for its ordinary purpose, although the Defendants knew, or should have known, that the DePuy Pinnacle did not meet the capabilities as represented and marketed; and/or

s. in that the Defendants breached their implied warranties of fitness for a particular purpose when they impliedly warranted to Plaintiff that the DePuy Pinnacle was fit for its ordinary purpose, although the Defendants knew, or

should have known, that the DePuy Pinnacle did not meet the capabilities as represented and marketed.

WHEREFORE, Plaintiff hereby demands judgment against the Defendants as follows:

A. Awarding Plaintiff past and future medical and incidental expenses, according to proof;

B. Awarding Plaintiff past and future loss of earning and/or earning capacity, according to proof;

C. Awarding Plaintiff past and future general or non-economic damages, according to proof;

D. Awarding punitive damages, pursuant to Connecticut General Statutes § 52-240b and other applicable laws, and exemplary damages in an amount to be determined at trial;

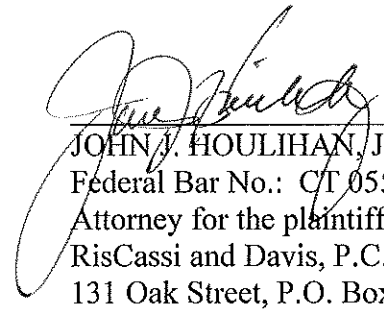
E. Awarding disbursements and expenses of this action, including reasonable counsel fees and other appropriate relief;

F. Awarding prejudgment and post judgment interest; and

G. Granting such other and further relief as is just and proper.

RISCASSI & DAVIS, P.C.

Dated: June 5, 2013



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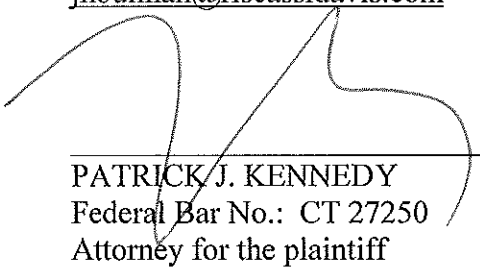

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues so triable.

RISCASSI & DAVIS, P.C.

Dated: June 5, 2013

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